



Regulation of Organ Transplants: A Comparison Between the Systems in the United States and Singapore

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**REGULATION OF ORGAN TRANSPLANTS: A COMPARISON BETWEEN
THE SYSTEMS IN THE UNITED STATES AND SINGAPORE**

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ABSTRACT

Organ failure is a devastating condition. Transplant offers the hope of “cure” to many patients with end-stage organ failures. The process of organ transplant is highly complicated involving many stakeholders. Important issues, including medical, legal, administrative and ethical, have to be resolved in order to implement a successful organ transplant system and prevent abuses. As such, legislative control of organ transplants is a necessity.

Most organ transplant laws cover the donation procedure, types of consent required, establishment of the transplant waiting lists, allocation of organs, certification of brain death, performance of the transplant procedure, and management of post-transplant issues. The regulatory system in the United States builds on the foundation of individual rights and explicit decisions are required for the donation of organs. The operations of the transplant system are largely outsourced to the Organ Procurement and Transplantation Network under a contractual agreement. In contrast, the Singapore system builds on a presumed consent mechanism where residents and citizens are automatically considered as donors upon their death unless they have registered an objection. The operations of the transplant system are centrally managed by the National Organ Transplant Unit within the Ministry of Health.

The two systems reflect the unique social and cultural backgrounds of the two countries and they meet the different needs of their people. However, recommendations are made for the United States to strengthen its regulatory system in terms of the need to regulate living donor organ transplants and expand the role of the Food and Drug Administration to ensure the quality and effectiveness of organs and tissues for transplantation.

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Aim

The aim of this paper is to discuss the general principles of organ transplant regulation and the need for legislative control of the organ transplant process, from the diagnosis of organ failure, setting up of transplant waiting lists, and procurement of organs, to the performance of the transplant procedure and management of post-transplant issues. I will then compare the two very different organ regulatory systems in the United States and Singapore, and discuss the strengths and weaknesses of these two respective systems.

Organ Failure

Organ failure is a devastating and yet common medical condition. It involves the failure of one or more essential organs or systems of the body, causing significant disabilities or even death. Organ failure can be a chronic problem requiring long term treatment, resulting in long term suffering of the patient and his family members, as well as the burden to pay for the high cost of treatment. On the other hand, it can be a relatively acute problem, with rapid deterioration of the patient's condition leading to death within a few weeks.

The common types of organ failure are kidney, liver and heart failures. For cornea, most medical authorities consider it a tissue and the reason for transplant is usually cornea opacity due to physical injuries, and not "failure" of the tissue. The aim of medical treatment is to provide "replacement therapy" – treatment that replaces the lost functions of the organ or system. To date, the only successful experience in providing replacement therapy is kidney dialysis. The other attempts to manage liver (e.g. liver dialysis) and heart failures (e.g. left

ventricular assist device; heart reconstruction surgery) have not produced very good results. Very often, these patients die relatively quickly even with therapy, unlike kidney failure patients who can live with dialysis for many years.

Organ Transplantation – A New Hope

A new hope for organ failure patients is transplantation. This involves taking the organ (or part of it, like a lobe of the liver) from another person and implanting it into the patient immediately after the diseased organ is removed. One of the biggest medical challenges of organ transplantation is graft rejection – the immune system of the patient's body recognizes the implanted organ or tissue as "foreign" and acts to reject it. With advances in immunosuppressive therapy, the problem of graft rejection could be more adequately controlled. For example, the introduction of cyclosporine by Novartis has greatly boosted the success rate of kidney transplantation.

Organ transplantation can be seen as a form of "cure" for organ failures as the patient receives a new functioning organ, and treatment is not aimed at salvaging or sustaining the diseased or failing organ. Even for kidney failure, which can be treated with dialysis, transplantation produces better results compared to dialysis in terms of longer survival and fewer complications.¹ For liver and heart failure patients, organ transplant is usually a life-

¹ Wolfe R A, Ashby V B, Milford E L et al (1999). Comparison of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, Recipients of A First Cadaveric Transplant. *New and England Journal of Medicine* Vol 342 No 23: 1725-1730

saving treatment as these patients could only be sustained for a relatively short period of time even in the best medical facilities, before they succumb to their diseases.

The first successful transplant (cornea) in the world took place in 1905 in now the Czech Republic by Eduard Zirm.² The first successful kidney transplant was performed in 1954 by Joseph Murray in Boston. The first successful liver transplant was performed in 1967 by Thomas Starzl in Denver. The first successful pancreas transplant was performed by Ruchard Lillehei and William Kelly in Minnesota in 1966. The first successful heart transplant was performed in 1967 by Christiaan Barnard in Cape Town.³ Subsequently, other types of transplants were tried and many were successfully performed, including lung, intestine, hand, face and even penis. Organ transplantation is an effective therapy for end-stage organ failure and is widely practiced around the world. According to the World Health Organization, kidney transplants are carried out in 91 countries. Around 66 000 kidney transplants, 21 000 liver transplants and 6000 heart transplants were performed globally in 2005. The access of patients to organ transplantation, however, varies according to their national situations, and is partly determined by the cost of health care, the level of technical capacity and, most importantly, the availability of organs.⁴

Most solid organs for transplantation are taken from deceased persons (cadaveric donors) – this is the safest way as the donor is already dead and will not be subjected to any medical risks. However, organs for transplantation must be “fresh” (functioning) and therefore

² Eye Bank Association of America: <http://www.restoresight.org/general/anniversary.htm>

³ Morris P J (2004). Transplantation: A Medical Miracle of the 20th Century. *Medical History* Vol 351:2678-2680.

⁴ World Health Organization (December 2007). *Bulletin of the World Health Organization* Vol 85 No 12.

timing is critical. It is usually not feasible to take organs from cardiac dead patients (i.e. donor's heartbeat and breathing have stopped) as their organs will rapidly deteriorate and there will not be sufficient time to prepare for and perform the transplant. The only exception is cornea, which can be taken from deceased patients even several hours after their deaths. For the other organs, they have to be taken from brain dead patients i.e. heart-beating donors. Although there have been attempts to harvest organs from non-heart-beating donors by a technique called "core cooling" (cooling the body rapidly to preserve the organs when the heart stops beating), there are tremendous logistic difficulties in implementing this on a large scale basis.

Currently there is a worldwide shortage of organs for transplantation. In the United States, it is estimated that the waiting list for organ transplant is nearing 100,000. Everyday, although there are about 77 people receiving an organ transplant, another 19 people on the waiting list die because there are not enough organs for transplantation.⁵

Besides taking organs from deceased people, organs can also be taken from living donors. The first living donor organ transplant was performed in Boston in 1954 involving the donation of one kidney to the patient from his twin brother (therefore overcoming the problem of graft rejection as immunosuppressive therapy was still undeveloped).⁶ In view of the severe shortage of organ for transplantation, many countries are encouraging living donor transplants. One kidney can be taken out for transplantation from a living person and the donor can live

⁵ US Department of Health and Human Services: <http://www.organdonor.gov>

⁶ Medical News Today (December 21, 2004). First Successful Living Donor Kidney Transplant 50 Years Ago. <http://www.medicalnewstoday.com/articles/18170.php>

without any significant adverse health effects with the remaining functional kidney. Liver can be split and one lobe donated to a patient. Pancreatic cells (Islet cells that produce insulin) can be taken out for implantation into type I diabetic patients although this is still considered by many as experimental.

There are a few other types of “transplants” such as bone marrow transplant and blood transfusion, but these are usually not considered as the same category as solid organ transplants (kidney, liver and heart) for regulatory purposes because they are readily replenished in the body of the donor and the procedures are of very low risk. There are also deceased people who donate their bones for use as bone grafts, as well as the whole body for educational (e.g. anatomical studies by medical students) and research purposes (e.g. experimental surgery)

Organ Transplant Process

The process to obtain human organs for transplantation is long and tedious, involving many different parties such as the patients, their family members, health care professionals, third-party payers (e.g. health insurance companies), government (as regulator and funders), community groups (e.g. religious institutions) and non-profit organizations (e.g. advocacy groups). Besides medical issues, there are also many social and ethical problems associated with organ transplants. As such, most countries have set up formal and informal systems to manage this process.

(A) Donor Side:

On the donor side, there must be full informed consent to donate (either by the donor himself or the next-of-kin). In some countries where there are presumed consent laws on organ donation, organs can be harvested from deceased people if they have not registered their objection. For living donors, it is even more complicated as the donor is subjected to a certain level of risk. The donor operative procedure is a major operation. The Mayo Clinic's transplant team estimates a risk of 0.5% - 1% to the liver donor's life.⁷ The donor is also at risk for temporary problems related to the surgical incision and the possibility of blood clots.

In the procurement stage, issues such as compromise on medical care of the identified donors (who are usually in the dying process), compensation to donor's family, and meeting particular religious requirements (e.g. Muslims must be buried within the same day before sunset) must be addressed. The most important non-medical question in organ transplant is whether there is any risk of organ trading, coercion or undue influence in the donation decision-making process. There are complex legal and ethical issues to consider and preventive measures are usually in place but difficult to enforced. For living donors, the risk of organ trading is especially high and some countries only allow immediate family members as living donors to ensure that that the donation is made out of altruistic motives.

At the point of harvesting the organ, the most critical issue is brain death certification as the doctors must be absolutely sure that the donor is dead as the procedure of removing the

⁷ <http://www.mayoclinic.org/liver-transplant/livingdonorlivertransplant.html>

organ will kill the donor if he is still alive. Although the brain death concept is accepted and treated to be equal to cardiac death by international medical professional bodies, some communities (e.g. certain Muslim sects) are still reluctant to accept the brain death concept. In practice, difficulty is often encountered when family members are asked to accept that their loved ones have died while they could still feel his heart beating. There must be clear protocols for the certification of death by designated doctors who are “neutral” to the care of the donor. Some countries stipulated specific sophisticated tests (e.g. cerebral angiography and radionuclide scan) to ascertain that the brain has stopped functioning permanently. The transplant team must also carefully evaluate whether the organ is suitable for transplant and whether there is a suitable recipient. Infectious diseases (e.g. HIV and hepatitis) must be screened. Finally, after the transplant, issues such as waiver of medical fees for the donor, reimbursement of funeral costs, and appreciation to donor’s family must be considered.

(B) Recipient Side

On the recipient side, the steps are equally complicated and many issues have to be addressed. First there must be clear diagnostic criteria to determine the patient’s condition and different options of treatment must be discussed with the patient. Not all patients are suitable for transplant (e.g. too sick, too many co-morbidities, etc), and a decision must be made on who can be placed on the transplant waiting list.

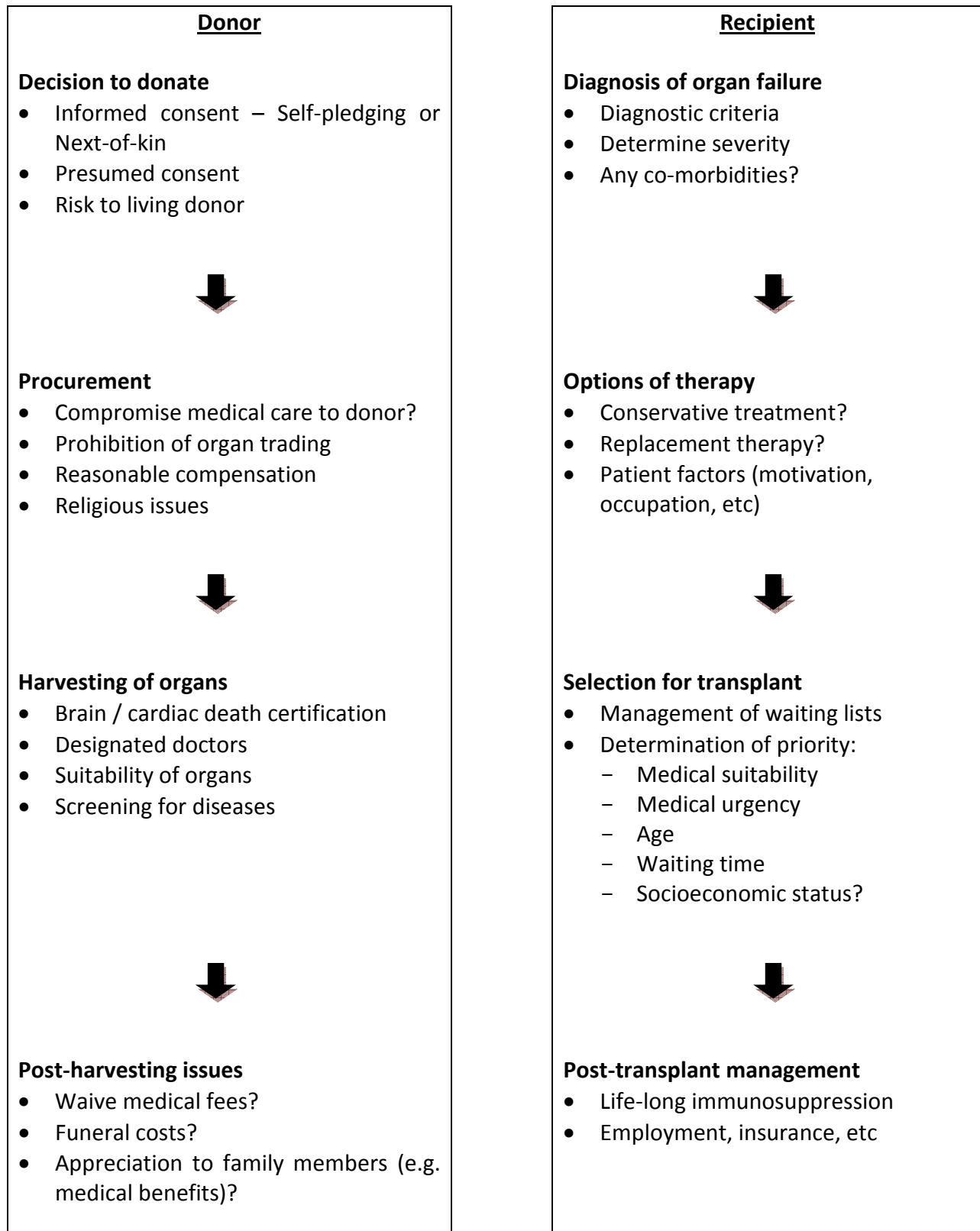
Generally, the most challenging task comes when an organ is available and decision-makers have to determine who gets and who does not get that organ. In view of the fact that the demand for organs greatly outstrips the supply of organs for transplantation, difficult

choices must be made all the time. The most important and obvious factor considered by health care institutions and doctors is the suitability of the recipient (e.g. immunologic matching and patient's medical condition). However, there are other issues such as medical urgency (e.g. whether a patient who is dying should have priority over a more stable patient who also needs the organ for life-saving purposes), age of patient (e.g. whether priority should be given to a young working father who is supporting a few dependents instead of a retired 80 years old person), amount of time spent waiting, and even socioeconomic status (e.g. whether priority should be given to a prominent leader of the community who has the potential to make important contributions to society instead of an ordinary citizen).

After the transplant, issues such as ensuring affordability of long term immunosuppressive therapy and medical follow up must be managed carefully so that the efforts of securing and transplanting the organ would not go to waste due to insufficient post-transplant support. Rehabilitation and psychological care of post-transplant patients are critical in reintegrating them back into society and helping them lead a normal life. If there is graft rejection, the subsequent care would be even more complicated as the patient may need to be re-routed for another transplant and the question of eligibility and priority would be raised in view of the long waiting list. Other issues such as discrimination at work and health insurance coverage would also have to be addressed, not only for the transplanted patients but also for the living donors.

Table 1 below summarizes the entire organ transplant process and lists the various issues to be considered on the donor side and the recipient side.

Table 1: Organ Transplant Process



The Need for Legislative Control

With such a complicated process and many difficult issues to be managed, organ transplant is clearly in need of some form of regulation to protect the interest of patients, manage the practice of health care professionals, and meet the expectations of society including the assurance of fairness and compliance with established ethical standards. The potential of abuse is very real as many who are in desperate need of organs may choose to obtain them by any means, including exploiting the “vulnerable” population such as the poor and those who have difficulty supporting their dependents. Leaving the system to professional oversight (e.g. medical organizations) would not be a feasible option.

The disparity between the demand and supply of organs for transplantation, as well as the fact that the demand is rather inelastic (i.e. the consumers are willing to pay almost any price to obtain the goods or services), has promulgated extensive national and local legislations and important case laws in many countries. Although these laws and regulations may complicate the efforts in obtaining organs, they are generally viewed by legislators, health care professionals, and the general public as a necessity. These laws attempt to regulate the scarce resource (transplantable human organs) and help establish equitable systems to allocate the organs where maximum benefits could be obtained, with specific objectives in four main areas:

1. **Medical** → Safety of patients and effectiveness of transplant
2. **Legal** → Prevention of abuse and protection of the public
3. **Administrative** → Equity of allocation and efficiency of the system
4. **Ethical** → Maintenance of public order and assurance of professionalism

Organ Transplant Laws

There are major differences in the laws for regulating organ transplants and related matters in different countries but they generally follow the same set of objectives and principles. This can be seen by categorizing the main issues to be addressed in these laws:

(1) Organ Donation

The law must specify how consent is to be taken, and if the deceased has not made a decision, who (e.g. the specific next-of-kin) has the authority to decide on his behalf. The two main consent systems are the opt-in (“informed consent”) system where people have to make a pledge to indicate clearly that they wish to be a donor; and the opt-out (“presumed consent”) system where people have to indicate and register their objections to be considered as non-donors – otherwise they will be automatically considered as donors at the time of their death. The method for determining death is usually spelt out (e.g. procedure for the certification of brain death) for the purposes of removing organs for transplantation from deceased donors.

The law will usually also specify which organs or tissues can be harvested and how these harvested organs and tissues is to be allocated (e.g. establishing a national prioritized queue system for recipients). The law may establish explicit rules or set up special committees to determine the allocation of organs.

Table 5 below summarizes the laws for the regulation of organ transplants in 34 countries.

TABLE 2: ORGAN DONATION LAWS IN 34 COUNTRIES

Country	Informed Consent Law	Presumed Consent Law
Australia	Law of 1982	
Austria		Law of 1982
Belgium		Law of 1986 (Families could potentially object)
Bulgaria		Law of 1996 (In practice consent is sought from the next-of-kin)
Canada	Law of 1980	
Croatia		Law of 2000 (In practice consent is sought from the next-of-kin)
Cyprus		Law of 1987
Czech Republic		Law of 1984
Denmark	Current Law of 1990	(Previous Law of 1967)
Finland		Law of 1985
France		Law of 1976 (In practice consent is sought from the next-of-kin)
Germany	Law of 1997	
Greece		Law of 1999
Hungary		Law of 1972
Ireland	No law, follows UK guidelines	
Israel		Law of 1953
Italy		Law of 1967
Japan	Law of 1997 (Before 1997, brain death not accepted) (Family can veto)	
Luxemburg		Law of 1982
The Netherlands	Law of 1996	
New Zealand	Law of 1964	
Norway		Law of 1973 (Family consulted and can potentially object)
Poland		Law of 1990
Portugal		Law of 1993
Romania	Law of 1998	
Singapore		Law of 1987 (Only Asian country with a presumed consent law)
Slovak Republic		Law of 1994
Slovenia		Law of 2000
Spain		Law of 1979 (In practice consent is sought from the next-of-kin)
Sweden		Law of 1996 (Family can potentially veto)
Switzerland	Law of 1996	
Turkey		Law of 1979 (Only Muslim-dominated country with a presumed consent law; in practice consent is sought from the next-of-kin)
United Kingdom	Laws of 1961 and 1989	
United States	Uniform Anatomical Gift Act of 1968, revised in 1987 National Organ Transplant Act of 1984	

Source: Alberto Abadie and Sebastien Gay (June 2004). The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study. Kennedy School of Government Working Paper No. RWP04-024.

(2) Transplant Procedures

The law may stipulate the qualifications of doctors who are allowed to perform transplant procedures. Many subsidiary regulations specify how matching of donor and recipient is to be carried out and which infectious diseases are to be tested before an organ can be used for transplantation. Some countries also have provisions in their laws to designate certain institutions for transplant procedures. The reason for doing this is mainly for quality control and to ensure that a sufficient number of cases are performed in every center to maintain clinical competence of the transplant teams.

(3) Organ Trading

At the Second Global Consultation on Human Transplantation of the World Health Organization's in March 2007, it was estimated that organ trafficking (i.e. patients went overseas to purchasing organs for transplantation) accounted for about 5% of the kidney transplants performed annually throughout the world.⁸ The law will usually ban any form of rewards (except reimbursement of expenses incurred in the process) to living donors (e.g. people who give away one kidney) or family members of deceased donors as most societies do not condone the sale of human organs or tissues. Organ trading is generally considered to be unethical except in one country – Iran – which has a legalized system for individuals to sell their

⁸ Shimazono Y (December 2007). The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information. *WHO Bulletin* Vol 85 No 12.

kidneys with a current market price of about US\$2,000 to US\$4,000. However, there were anecdotal reports indicating wide spread exploitation of the poor in this system.⁹

(4) Living Donors

Besides organ trading, there are many ethical issues involving live donors in transplantation. The main concern is the potential risk to the donors. The law will therefore specify how the potential donor must be assessed, including psychiatric evaluation to ensure that the donor is of sound mind and is fully informed of the nature and consequences of organ donation and transplantation, and that the decision is made out of altruism without coercion or undue influence. Most laws ban all forms of monetary transactions between the recipient and the donor except basic compensation such as traveling costs and loss of income. Sometimes, the law allows only closed relatives of the recipient to donate to prevent organ trading.

(5) Societal Norms

In some countries, the law may address issues relating to culture and religion in the community and accommodate different practices. For example, certain subgroup of the population may object to organ donation (e.g. Jehovah Witness) or that permission must be obtained from certain family members (e.g. Muslims who may be required to obtain permission from their *waris* – the paternal next-of-kin). In some Catholic countries where the opinions of the family are considered to be as important as the expressed wish of the deceased, legal or

⁹ Corwin J A (2005). Organ Trafficking Turns Poor / Rich into Supply / Demand. *Albion Monitor* <http://www.albionmonitor.com/0605a/organtraffickrichpoor.html>

administrative provisions are made in the law to allow family members to veto the decision to donate organs made by the deceased.

(6) Administrative Agency – Some laws assign the duty of regulating organ transplants to the usual health authorities (e.g. Ministry / Department of Health) while some establish special agencies to administer the laws. For example, in the United Kingdom, a special unit – the Human Tissue Authority – is set up to oversee all organ transplant matters including the approval of living donor organ transplants. In some countries, the law is silent and the relevant health authorities could exercise greater flexibility, such as the United States Department of Health and Human Services, that contracts with the OPTN (Organ Procurement and Transplantation Network) to formulate organ transplant policies and coordinate organ donation and transplantation.

Regulation of Organ Transplants in the United States

As of April 2008, there are nearly 100,000 people in the United States waiting for an organ transplant. The needs for organs and transplants are rising every year. The efficiency and effectiveness of the organ transplant system is closely linked to the laws governing it. The key feature is the opt-in system for organ donation with operational flexibility at the state level.

Waiting list candidates	99,093	As of Apr 30, 2008
Transplants January - April 2008	2,197	As of Apr 30, 2008
Donors January – April 2008	1,132	As of Apr 30, 2008

Source: Organ Procurement and Transplantation Network (OPTN) data

Following is a survey of the various laws related to the regulation of organ transplants in the United States.^{10, 11, 12, 13, 14}

1968 – Uniform Anatomical Gift Act

There were no federal laws regulating organ and tissue donation before 1968. Organ and tissue donations were handled at the state level only. Unfortunately, these state laws differed considerably from state to state and caused a lot of confusion. The Uniform Anatomical Gift Act was enacted in 1968 to address these problems by providing a framework of uniform laws in the United States relating to organ and tissue transplantation. It also attempted to increase the number of available organs by making it easier for individuals to pledge as organ donors.

In 1972, the Uniform “Organ Donor Card” was mandated to be recognized as a legal document in all 50 states under the Uniform Anatomical Gift Act. This empowered any person aged 18 years and above to legally make a pledge to donate his organs upon death.

¹⁰ eNotes: Encyclopedia of Everyday Law: Organ Donation. <http://www.enotes.com/everyday-law-encyclopedia/organ-donation>

¹¹ United States Department of Health and Human Services. OrganDonor.Gov: Access to U.S. Government Information on Organ and tissue Donation and Transplantation. <http://www.organdonor.gov/>

¹² Donate Life America Website. <http://www.donatelife.net/>

¹³ Lectric Law Library's Stacks: Organ Donation. <http://www.lectlaw.com/files/qfl03.htm>

¹⁴ OPTN (Organ Procurement and Transplantation Network) Website. <http://www.optn.org/>

1984 – National Organ Transplant Act (NOTA)

The NOTA establishes the framework for the Organ Procurement and Transplantation Network (OPTN) at the national level. The Scientific Registry of Transplant Recipients, a government unit within the Public Health Service (Division of Transplantation), oversees the contractual arrangements with the OPTN. Under the NOTA, the buying and selling of organs are prohibited. However, payment of “the expenses of travel, housing, and lost wages incurred by the (living) donor” is expressly permitted in section 301.

1987 – Uniform Anatomical Gift Act (Amended)

This version of the UAGA includes several amendments to the original law enacted in 1968 aiming to facilitate organ donation by providing a useful and uniform legal environment throughout the country.

1991 – Patient Self-Determination Act

The federal Patient Self-Determination Act (PSDA) empowers and promotes the use of advance directives such as living wills and durable powers of attorney for health care. The PSDA changes key provisions in federal Medicare and Medicaid laws.

There are three kinds of documents that may serve as evidence of a person's wish to donate his organs in the event of that person's death:

- **Living wills:** Detailed regulations of living wills are found in state statutes. Living wills provide instructions for the person's medical care if he becomes incapacitated or unable to

make decisions himself. In most cases, a living will can stipulate that the person's organs or tissues be removed and donated for medical purposes if they were found to be suitable. Individuals who are making a living will are usually advised to inform their physicians and family members.

- **Durable powers of attorney for health care:** A durable power of attorney for health care names someone as his "agent" who shall make important decisions on health care matters concerning that person should the person become incapacitated. This document can also instruct the agent to donate the person's organs or tissues upon the person's death. As with living wills, the durable power of attorney for medical care is only useful if the agent, the family members and the attending physician of the person are aware of its existence.
- **Advanced care medical directive:** An advance care medical directive (ACMD) combines some features of the living will and the durable power of attorney for health care. An ACMD allows individuals to give instructions on the types of care they want to accept or reject in different number medical scenarios. These documents need to be created in consultation with the physician so that it could be of practical use in medical practice.

1999 – Organ Donor Leave Act

This law makes provisions for donors who are federal employees to enjoy organ donor leave – seven days for bone marrow donation and 30 days for solid organ donation.

1999 – Organ Procurement and Transplantation Network Final Rule

This document sets forth improvements made to the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) which were published in 1998. The purpose of the final rule is to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation.

2000 – Children's Health Act

This law amends the Public Health Service Act and uses the Organ Procurement and Transplantation Network to address the special needs of children under the age of 18 years by adopting criteria, policies, and procedures that address the unique healthcare needs of children, including transplant matters. The law requires the OPTN to carry out studies and undertake projects to improve procedures for organ donation procurement and allocation, including those children with special needs, minority groups, and those with limited access to transportation. The law also provides for a study to determine the costs of immunosuppressive drugs to children and the extent that health insurance plans cover such costs.

2004 – Organ Donation and Recovery Improvement Act

Under this Act, funding is made available to states for the following purposes:

- Support organ donation awareness programs, public education and outreach programs aiming to increase the number of organ donors (including living donors), and the development of and dissemination of educational materials to inform healthcare

professionals and other relevant professionals on matters regarding organ, tissue, and eye donation;

- Enable qualified organ procurement organizations and hospitals to establish programs to increase the rate of organ donation;
- Provide financial assistance to living donors to help defray travel, subsistence, and other incidental non-medical expenses;
- Establish mechanisms to evaluate the long-term effects of living organ donation.

New Donation Laws

Many states and other jurisdictions are in the process of implementing measures designed to make it easier for organ donations to occur. Some of the important changes include expanding the list of people who can consent to an unconscious patient becoming a donor and making it clear that a person's decision to be an organ donor cannot be revoked by anyone else.¹⁵

Regulation of Organ Transplants in Singapore

Singapore is a small island city-state in Southeast Asia with an area of 683 squared kilometers (about 3.5 times the size of Washington DC). It was founded as a British trading colony in 1819. It joined the Malaysian Federation in 1963 but separated later and became independent in 1965. Singapore subsequently became one of the world's most prosperous

¹⁵ Stein R (April 4, 2007). States Revising Organ Donation Law. *Washingtonpost.com*. <http://www.washingtonpost.com/wp-dyn/content/article/2007/04/03/AR2007040302062.html>

countries with strong international trading links with one of the world's busiest port (in terms of tonnage handled) and per capita GDP (US\$31,400 in 2006) equal to that of the leading nations of West (e.g. UK = US\$31,800 in 2006).

The size of Singapore population is about 4.5 million people but only 3.5 million people are residents and citizens while the rest are mainly foreigners working in Singapore. The three main ethnic groups are Chinese (77%), Malay (14%) and Indian (8%). The main spoken languages are Mandarin (35%), English (23%), Malay (14.1%), various forms of Chinese dialects (Hokkien 11.4%, Cantonese 5.7%, Teochew 4.9%), and Tamil (3.2%). However, English is the administrative language and the language of instruction used in educational institutions. According to the Census of 2000, the main religious groups are: Buddhist 42.5%, Muslim 14.9%, Taoist 8.5%, Hindu 4%, Catholic 4.8%, Protestant Christian 9.8%, other 0.7%, and no religion 14.8%.

The first organ donation law in Singapore was passed in 1972 – the Medical (Therapy, Education and Research) Act (MTERA),¹⁶ which allows the donation of human organs and tissues for transplant, medical education (e.g. dissection) and research purposes. This is an opt-in system. However, from 1972 to 2003, only 55,000 pledges were received despite continuous efforts in promoting organ donation. Of these 55,000 pledges, only three became kidney donors (providing 6 kidneys) in the last 30 years, benefiting 6 recipients. This will not address the needs of the 1000 new cases of organ failure patients every year. Many patients die or drop

¹⁶ The Republic of Singapore (1972). The Medical (Therapy, Education and Research) Act. <http://agcvldb4.agc.gov.sg/>

out (become unfit for transplant when the disease progresses) from the list while waiting. Currently, there are more than 500 people on the transplant waiting list (most are for kidney transplant and the numbers for liver and heart transplants are very small as these patients die very quickly).

In 1987, the Government decided to introduce a different system – the opt-out system – under the Human Organ Transplant Act (HOTA).¹⁷ The HOTA is the first and only presumed consent organ donation law in Asia. When the law was enacted in 1987, it only covered the kidney and deaths from accidents (because these were more acceptable to the public and other types of organ transplants were still not fully established yet) and the kidneys harvested could only be used for transplant purposes. People could continue to pledge for organ donation under the MTERA for organs other than the kidney and it would include non-accidental deaths; the purposes would include transplant, education and research.

With better safety measures implemented and the increasing need for other types of organs for transplants (i.e. liver, heart and cornea), the HOTA was amended in 2004 to expand its coverage to include the heart, liver and cornea, and all causes of death (instead of accidents only). The amendment also added the regulation of living donor organ transplantation (which was previously practiced according to professional guidelines issued by the Ministry of Health without legislative control). With the expansion of the scope of HOTA, the role of MTERA has gradually diminished. Currently, the HOTA system produces about 30 donors every year,

¹⁷ The Republic of Singapore (1987). The Human Organ Transplant Act. <http://agcvldb4.agc.gov.sg/>

implying 60 kidney patients, 30 heart patients, 30 liver patients, and another 30 – 60 cornea patients, are benefiting from these “gifts of life”.

The HOTA covers all Singapore citizens and permanent residents aged 21 to 60 years. The Act originally excluded Muslims on religious grounds but this was changed in an amendment in January 2008 and all Singapore residents and citizens, regardless of their religious affiliations, are now covered under the HOTA. Those who do not wish to be donors have to register their objection with the Ministry of Health. Every year, two batches of letters will be sent to Singapore citizens and permanent residents who are reaching 21 years old to inform them of the need for organ donation to save lives, as well as the details of the presumed consent law, including the opt-out mechanism. In order to ensure that the letters reach them, the methods of mailing have improved over the years and at present, these letters are sent by courier (i.e. by hand) to the addressees so that nobody could claim that he / she is unaware of the presumed consent law. Continuous educational programs are also run twice every year to coincide with the mailing out of the two batches of notification letters. The programs include advertisements in the major newspapers, talks, exhibitions, etc. There are also special events such as the annual game for organ transplant patients (i.e. patients who have received a transplant), which is aimed to demonstrate the new lease of life they receive through organ donation and transplantation – a “gift of life” from other people.

As a principle of fairness, objectors to the HOTA have lower priority in receiving organs harvested under the system if they happen to develop organ failure. Before the 2008 amendment, Muslims also had lower priority like the objectors unless they had made a pledge

to be organ donors under the MTERA opt-in system. For people who are given lower priority under the HOTA system, their chances of receiving an organ for transplant if they ever need it, are near zero because of the large number of patients who have priority over them in the waiting list.

The Singapore case is a good example to demonstrate the impact of legislation in helping organ failure patients and saving lives. Table 3 below shows the effects of the 2004 amendment of the Human Organ Transplant Act on the transplant waiting lists and the number of transplants performed.

Table 3: Effects of the Amendment of the Human Organ Transplant Act in 2004

Type of Transplant	Number of People on Waiting List	Number of Transplants Performed
Kidney	<ul style="list-style-type: none"> • 557 in 2006 • Down from the peak of 673 in 2003 	<ul style="list-style-type: none"> • In 2006, 43 live and 53 cadaveric transplants performed • In 2003, 18 live and 26 cadaveric transplants performed
Liver	<ul style="list-style-type: none"> • 12 in 2006 • Down from the peak of 22 in 2003 	<ul style="list-style-type: none"> • In 2006, 7 live and 25 cadaveric transplants performed • In 2003, 2 live and 17 cadaveric transplants performed
Heart	<ul style="list-style-type: none"> • 1 in 2006 • Down from the peak of 7 in 2002 	<ul style="list-style-type: none"> • In 2006, 6 transplants performed • In 2003, no transplant performed

Source: Ministry of Health, Singapore Ministry of Health, Singapore (2007). Human Organ Transplant Statistics. <http://www.moh.gov.sg/mohcorp/programmes.aspx?id=12494>

Comparing the Key Features of the United States and Singapore Systems

The organ transplant system in the United States functions on an opt-in basis with a coordinated network to allocate organs for transplantation. The network is operated by the OPTN (Organ Procurement and Transplantation Network), which is contracted by the Department of Health and Human Services. This approach will have to emphasize public outreach and educational efforts to convince as many people as possible to pledge as organ donors.

The American system reflects the long-standing liberal democratic tradition of the country. It is unlikely to be acceptable to most Americans to implement a presumed consent system involving the removal of organs from individuals without their explicit consent. In addition, the political philosophy of restricting the power of the government has probably restrained the Department of Health and Human Services to play an active role in managing organ transplantation, which is seen by many as a clinical issue to be managed at the ground level by the professionals.

The Singapore system, in contrast, functions on an opt-out basis with a centralized National Organ Transplant Unit within the Ministry of Health to manage the transplant waiting lists and oversee all transplant processes. The approach is to constantly remind the public of the presumed consent law, especially those who are new to the system (i.e. people turning 21 years old and the new residents of Singapore), and ensure that the harvesting procedure is carried out efficiently.

Singapore has a one-party dominated government in the past 30 years. The “aggressive” approach is more acceptable to a population that is accustomed to complying with government orders. The social culture also places great emphasis on pragmatism and outcome. As such, even if the processes may be debatable in terms of respecting individual rights, they are usually tolerated by the people if they could produce better outcomes. In this case, the opt-out system has clearly demonstrated its effects in boosting transplant rates and saving lives. The government has explained publicly that the presumed consent system is a desperate solution to a desperate problem.

Table 4 below shows the detailed comparison of the two organ transplant regulatory systems.

Table 4: A Comparison of the Organ Transplant Regulatory Systems in the United States and Singapore

Regulatory Areas	United States	Singapore
Organ Donation	<ul style="list-style-type: none"> • Opt-in / Informed consent • Administered at state level 	<ul style="list-style-type: none"> • Opt-out / Presumed consent • Administered centrally by the Ministry
Organ Procurement	<ul style="list-style-type: none"> • Contracted out to OPTN 	<ul style="list-style-type: none"> • Centralized unit in the Ministry
Types of organs and tissues for Transplant	<ul style="list-style-type: none"> • Not regulated 	<ul style="list-style-type: none"> • Specified in the legislation
Living Donor Transplant	<ul style="list-style-type: none"> • OPTN policies – best practices and voluntary guidelines 	<ul style="list-style-type: none"> • Legislated control requiring approval of Transplant Ethics Committee
Organ trading	<ul style="list-style-type: none"> • Prohibited (reasonable compensation allowed) 	<ul style="list-style-type: none"> • Prohibited (reasonable compensation allowed)

Policy Recommendations

The first and utmost question to ask after comparing the two systems is whether the United State should consider an opt-out system in view of the increasing needs for organ transplant. In the study conducted by Abadie and Gay¹⁸ to assess the impact of presumed consent laws on donation rates, they constructed a dataset on organ donation rates and potential factors affecting organ donation for 22 countries over a 10-year period and found that while differences in other determinants of organ donation explained much of the variation in donation rates, after controlling for those determinants. They concluded that presumed consent legislation had a positive and sizeable effect on organ donation rates. There is great support for the presumed consent system in various countries, especially in view of the practical advantages. Straw¹⁹ (Founder and Chairman of the Organ Donor Association of Australia) argues that presumed consent legislation gathers up those who will donate but who find the procedures involved too time consuming, whilst at the same time it allows a legitimate avenue for others to deny their donation. His organization is proposing to the Australian Government that Australia should adopt the presumed consent system because of its relatively low transplant rates and the high cost of dialysis compared to transplant. In the United Kingdom, about 7,500 people are on the transplant waiting list.²⁰ About 400 people on the

¹⁸ Alberto Abadie and Sebastien Gay (June 2004). The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study. Kennedy School of Government Working Paper No. RWP04-024.

¹⁹ Straw D C (2004). Opting-Out Legislation. The Organ Donor Association, Australia:

<http://www.multiline.com.au/~donor/index.html>

²⁰ UK Transplant: <http://www.uktransplant.org.uk/ukt/>

waiting list die each year while waiting for a transplant (excluding those who did not even reach the waiting list). The British Government is considering legislative changes to move towards an opt-out system. The British Medical Association (BMA) also supports a system of presumed consent with safeguards, for those over the age of 16 years, where relatives' views are taken into account. The BMA believes that moving into a system of presumed consent, combined with other reforms to the transplant infrastructure, would play an important part in improving the organ donation system so that more lives can be saved.²¹ In order to gauge the response of the public, the BMA recently conducted a survey with 2,000 people in England, Scotland and Wales, showing that only about a quarter were on the Organ Donor Register although 62% were willing to donate their organs for transplantation after death and 64% were supportive of a presumed consent system.²² The Chief Medical Officer for England, Sir Liam Donaldson, recently called for organ donation in England and Wales to move towards an opt-out system.²³

Courtney (Vice President of the United States Presumed Consent Foundation) believes that implementing an opt-out system is the fastest and least expensive way to reduce the shortage of organs for transplantation in the United States with no harm to anyone.²⁴ He

²¹ British Medical Association (October 2007). Presumed Consent for Organ Donation.

<http://www.bma.org.uk/ap.nsf/Content/OrganDonationPresumedConsent>

²² If I Should Die.co.uk (October 2007). BMA Survey Shows 64% Favour 'Presumed Consent' Organ Donation: <http://www.ifishouldie.co.uk/bma-survey-shows-64-favour-presumed-consent-organ-donation-i8.html>

²³ BBC News, International Version (July 17, 2007). Everyone Should Donate Organs:

<http://news.bbc.co.uk/2/hi/health/6902519.stm>

²⁴ Courtney D W (2007). Your Choice First! A Presumed Consent Policy for Organ Donation. The Presumed Consent Foundation Website: <http://www.presumedconsent.org/>

proposes that a presumed consent policy could be successfully implemented with four areas of integral capabilities: (1) notification, education, and awareness; (2) a central registry; (3) proper program management; and (4) strong oversight to guard against abuses. The current position of the American Medical Association (AMA) on presumed consent is that the concept is not unethical, but there has to be a foolproof opt-out system.²⁵ Gill acknowledges the ethical concerns that people's organs might be removed against their wishes in an opt-out system since some would not bother to register their objections. However, he argues that it is morally no worse if we do not remove organs from the bodies of people who wish to donate but did not bother to sign up in an opt-in system and he believes there are more people in this category. As such he suggests that a policy of presumed consent for organ donation in the United States would be a moral improvement over the current system.²⁶ Davis argues that although increased public education to increase consent to donate and maximize opportunities to donate may yield modest success, if progress continues at that pace, the gap between supply and demand will take years to close and thousands of Americans will continue to die while on organ waiting lists. As such, he calls for bold action by government to solve the problem and recommends two particular policies: mandated choice (e.g. when a person renews his driver's license or files an income tax return, he would be "forced" to indicate a choice on whether he wants to be a donor) and presumed consent.²⁷

²⁵ AMNews (July 5, 2004). American Medical Association Backs Review of Presumed Consent on Organ Donations. *The Newspaper for America's Physicians*: Amendnews.com

²⁶ Gill M B (2004). Presumed Consent, Autonomy, and Organ Donation. *Journal of Medicine and Philosophy* Vol 29 No 1.

²⁷ Davis R M (1999). Meeting the Demand for Donor Organs in the U.S.: It's Time for Bold Public Policy, Such as Mandated Choice or Presumed Consent. *British Medical Journal* Vol 319(7222): 1382-1383.

In my opinion, I do not think the presumed consent system would work in the United States at this point in time in view of its liberal democratic tradition and the long history of respecting individual rights. Although many of the presumed consent systems are found in the West – mainly the Western European countries, their societies are different as they are usually made up of homogenous people with a long history of authoritarian rule under various monarchs. There has not been sufficient public discussion on this subject in the United States and most Americans are probably not aware of the difference between the two systems. Any proposal on a presumed consent law would be unlikely to even stand a chance for consideration by any legislator. However, there should be on-going dialogues and debates on this important issue and the opinions of the public should be systematically determined and analyzed over time. If there is greater acceptance of a presumed consent system in the future, large-scales studies should be carried out to provide information to guide policy-makers.

Some have also advocated that the United States should implement a “controlled organ trading system” like the one in Iran to solve the acute problem of organ shortage.²⁸ Prohibition of organ trading is mainly an ethical issue. The great majority of human societies do not condone the buying and selling of human beings or their parts as this concerns the sanctity of the human body and the exploitation of the poor. It is a value cherished by most people and lifting the ban is unlikely to gain any significant support from the American public. Moreover, the United States is relatively more religious than most developed countries (such as those in Europe) and organ trading would be frowned upon by most mainstream religions.

²⁸ Hippen B E (March 20, 2008). Organ Sales and Moral Travails: Lessons from the Living Kidney Vendor Program in Iran. *Policy Analysis* No. 614. Washing D.C.: Cato Institute.

However, in my opinion, there are two other issues which should be considered for more formal regulation in the United States: the regulation of living donor organ transplants and the regulation of organ and tissues used for transplant purposes. Currently, the Organ Procurement and Transplantation Network formulates policies regarding living donor organ transplants (except organ trading, which is prohibited under the National Organ Transplant Act of 1984). However, these policies are only considered as best practices or guidelines for voluntary compliance. There are also more and more complicated and new processes involved in living donor organ transplants. For example, U.C.S.F. (University of California, San Francisco) runs a “Donor Waiting List Exchange Program” where a donor could donate to a patient on the waiting list in exchange of moving his own relative (organ does not match) up the waiting list.²⁹ Johns Hopkins Comprehensive Transplant Center performed the first “Triple Swap” kidney transplants in 2003 where 3 different donors exchange their donated kidney so as to find a better match for their respective relative on the waiting list. All these initiatives involve significant risks and complicated operational and ethical issues. Laws must not lag behind practice too long. It is timely to consider legislative control for living donor organ transplants in the United States where most of these new cutting-edge initiatives take place.

The last issue is the regulation of organ and tissues used for transplant purposes. The United States has one of the most advanced and comprehensive regulatory systems in the world for drugs, medical devices, and biologics. Human organs and tissues implanted into human bodies for therapeutic purposes cannot be considered to be different from drugs and

²⁹ UCSF Medical Center. Specialized Services: Kidney Donor waiting List Exchange. <http://www.ucsfhealth.org/adult/special/k/27285.html>

biologics. There are many reports regarding transplant-acquired infections including AIDS, hepatitis and dengue, which was first reported in Singapore in 2005.³⁰ The quality and effectiveness of organs and tissues affects the outcome of transplants directly and these organs and tissues should therefore be formally regulated. The regulation should cover the screening for infectious diseases, sources of organs (local and overseas, as well as animal sources – “xenotransplantation”), methods for obtaining the organs and their transportation, conditions for preservation and storage, and indications for use. The Food and Drug Administration (FDA) should play a more active role in the regulation of organ and tissues in these areas. However, there must be clear legislative support for FDA to perform these functions.

Conclusion

Organ transplant is the ultimate hope to many who have end-stage organ failures. To some, it is a life-saving procedure. However, taking and implanting the organ from one human being to another is a highly complicated and sensitive subject. It involves medical, legal, administrative and ethical issues that must be resolved before society could accept the practice. Very often, the cultural values and religious practices in a particular community will have important influence on its system of organ transplant regulation.

The main objective of legislation is to protect public interest and maintain public order. The outcomes policy-makers hope to see are the increased availability of human organs for transplantation so as to relieve suffering and save lives, and the proper performance of

³⁰ Tan F L S, Loh D L S K, and Prabhakaran K (2005). Dengue Haemorrhagic Fever After Living Donor Renal Transplantation. *Oxford Journal on Nephrology, Dialysis, and Transplantation* Vol 20 No 2.

transplants in an orderly and acceptable manner in the context of the local community. As such, establishing laws to regulate organ transplants is a highly sensitive and political exercise that must be handled with care. A balanced system should be created that is clinically effective (meeting patients' needs), legally sound (maintaining order), administratively efficient (achieving good quality at affordable costs), and ethically acceptable (resulting in a harmonious society).

The rationales for regulating organ transplants are well established. However, the systems adopted in different countries or even at different regions within a country can be vastly different. They reflect the different value systems in these societies. The United States, having a liberal democratic tradition and a strong belief in individual rights, adopts a system based on clear individual conviction for organ donation. In Singapore where there is a strong trust in the government / establishment where people comply readily with governmental policies and consider societal goals to be above personal rights, a presumed consent system is adopted. The unique background in each of the two countries explains the different approach adopted. Although the presumed consent system is generally considered to be more effective in increasing the supply of organs for transplantation, it would not be prudent to impose this system on any country. Each society must decide for itself what is acceptable, and accept the consequences. These are difficult policy choices and trade-offs inevitably have to be made regardless of which system a country decides to adopt.

However, there are certain universal regulatory principles that could be applied regardless of the type of regulatory system adopted. One example is the regulation of organs

and tissues for transplantation. In this regard, the objective is simple and straightforward – to protect the patients. The United States should consider a more comprehensive regulatory system for such “health products”. With the appropriate legislative backing, the role of the FDA should be expanded to cover this area.

[END]